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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,984	10/13/2000	Shaw-Fen Sylvia Hu	A-357B	1047

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EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/08/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/687,984

Applicant(s)

Hsu

Examiner

Stephen Buckler

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/22/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 111; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 30 + 45-50 is/are pending in the application.
- Of the above claim(s) 47-50 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 30 + 45-46 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The disclosure is objected to because of the following informalities: the specification on page 2, lines 11-12; page 11, lines 12 and 27-28; page 16, line 10; page 17, line 11; page 38, line 7; and page 47, lines 35-36 requires updating: please update any change in the status (abandoned, issued Patent No., etc.) of US Patent Application Nos. 08/182,183, 07/501,904, 07/576,316, and 07/855,413.

Appropriate correction is required.

3. The communication filed 4/22/03 is not fully responsive to the Office communication mailed 10/21/02 for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules or CRF Diskette Problem Report. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). The claims must be amended to reflect that the elected invention of Group I is wherein X is SEQ ID NO:18, as elected in Paper No. 7. The claims have and will be examined only to the extent that X is SEQ ID NO:18. Applicant must fully comply with both the sequence rules and all of the outstanding double-patenting rejections in order to be bona fide responsive to this Office Action.

4. Claims 47-48 are withdrawn as belonging to the non-elected invention.

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5. Claims 30 and 45-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over: (a) claims 1, 4, 10, 12, and 20 of US 5,929,041; (b) claims 1 and 5 of US 5,837,681; (c) claims 1 and 3 of US 5,731,284; (d) claims 1, 3, and 8 of US 5,641,750; and (e) claims 1, 3, and 16 of US 5,641,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because the open language of the instant claims reads on full length GDNF and/or 70% identity to GDNF protein products of the patents, and the actual process of administering the GDNF protein product is the same between the instant claims and the patented claims (*Ex parte Novitski*, 26 USPQ 1391).

Applicant's arguments filed 4/22/03 have been fully considered but they are not persuasive because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but where the examined application claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims. See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 646 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are sub-generic to all that is recited in the claims under examination. That is, the patented claims fall entirely within the scope of the examined claims or, in other words, the examined claims are all anticipated by the patented claims. Specifically, all of the patented

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claims recite methods of administering GDNF (SEQ ID NO:1) protein product or sequences that share 70% identity with GDNF (SEQ ID NO:1) for treating cholinergic neurons, auditory neurons, retinal neurons, etc. The claims under examination recite methods of administering a fragment of GDNF (SEQ ID NO:1) or sequences that share 70% identity with the instant fragment using open language (instant claim 30: "...administering a pharmaceutical composition comprising...") to treat neurons so that the instant claims completely encompass and are broader in scope than the patented claims. The patented sub-genus claims anticipate the instant genus claims, and allowing the instant claims would extend the patent term protection of the patented sub-genus claims. The instant genus claims are anticipated by the patented sub-genus claims in the same manner that a genus claim is anticipated by and/or is obvious over a species claim. A terminal disclaimer or amending the instant claim language from open to closed would obviate the grounds of this rejection.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

August 6, 2003

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600